

POLYMYXIN B SULFATE AND TRIMETHOPRIM- polymyxin b sulfate and trimethoprim sulfate solution/ drops
Preferred Pharmaceuticals Inc.

**Polymyxin B Sulfate
and Trimethoprim
Ophthalmic Solution, USP
(Sterile)**

Rx only

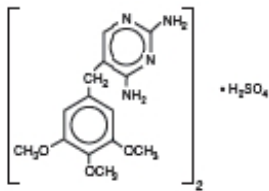
FOR TOPICAL APPLICATION IN THE EYE

DESCRIPTION

Polymyxin B sulfate and trimethoprim ophthalmic solution, USP is a sterile antimicrobial solution for topical ophthalmic use. It has pH of 4.0 to 5.5 and osmolality of 270 to 310 mOsm/kg.

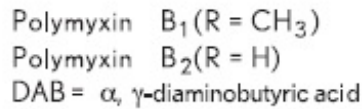
Chemical Names:

Trimethoprim sulfate, 2,4-diamino-5-(3,4,5-trimethoxybenzyl) pyrimidine sulfate, is a white, odorless, crystalline powder with a molecular weight of 678.72 and the following structural formula:



C₂₈H₃₈N₈O₁₀S Mol. Wt. 678.72

Polymyxin B sulfate is the sulfate salt of polymyxin B₁ and B₂ which are produced by the growth of *Bacillus polymyxa* (Prazmowski) Migula (Fam. Bacillaceae). It has a potency of not less than 6,000 polymyxin B units per mg, calculated on an anhydrous basis. The structural formula is:



Polymyxin B: *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter aerogenes* and *Haemophilus influenzae*.

INDICATIONS AND USAGE

CONTRAINDICATIONS

PRECAUTIONS

General

As with other antimicrobial preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be initiated.

Information for Patients

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: Long-term studies in animals to evaluate carcinogenic potential have not been conducted with polymyxin B sulfate or trimethoprim.

Mutagenesis: Trimethoprim was demonstrated to be non-mutagenic in the Ames assay. In studies at two laboratories no chromosomal damage was detected in cultured Chinese hamster ovary cells at concentrations approximately 500 times human plasma levels after oral administration; at concentrations approximately 1,000 times human plasma levels after oral administration in these same cells, a low level of chromosomal damage was induced at one of the laboratories. Studies to evaluate mutagenic potential have not been conducted with polymyxin B sulfate.

Impairment of Fertility: Polymyxin B sulfate has been reported to impair the motility of equine sperm, but its effects on male or female fertility are unknown.

No adverse effects on fertility or general reproductive performance were observed in rats given trimethoprim in oral dosages as high as 70 mg/kg/day for males and 14 mg/kg/day for females.

Pregnancy

Teratogenic Effects

Animal reproduction studies have not been conducted with polymyxin B sulfate. It is not known whether polymyxin B sulfate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

Trimethoprim has been shown to be teratogenic in the rat when given in oral doses 40 times the human dose. In some rabbit studies, the overall increase in fetal loss (dead and resorbed and malformed conceptuses) was associated with oral doses 6 times the human therapeutic dose.

While there are no large well-controlled studies on the use of trimethoprim in pregnant women, Brumfitt and Pursell, in a retrospective study, reported the outcome of 186 pregnancies during which the mother received either placebo or oral trimethoprim in combination with sulfamethoxazole. The incidence of congenital abnormalities was 4.5%

(3 of 66) in those who received placebo and 3.3% (4 of 120) in those receiving trimethoprim and sulfamethoxazole. There were no abnormalities in the 10 children whose mothers received the drug during the first trimester. In a separate survey, Brumfitt and Pursell also found no congenital abnormalities in 35 children whose mothers had received oral trimethoprim and sulfamethoxazole at the time of conception or shortly thereafter.

Because trimethoprim may interfere with folic acid metabolism, trimethoprim should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects

The oral administration of trimethoprim to rats at a dose of 70 mg/kg/day commencing with the last third of gestation and continuing through parturition and lactation caused no deleterious effects on gestation or pup growth and survival.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when polymyxin B sulfate and trimethoprim ophthalmic solution is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children below the age of 2 months have not been established (see **Error! Hyperlink reference not valid.**).

Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

ADVERSE REACTIONS

The most frequent adverse reaction to polymyxin B sulfate and trimethoprim ophthalmic solution is local irritation consisting of increased redness, burning, stinging, and/or itching. This may occur on instillation, within 48 hours, or at any time with extended use. There are also multiple reports of hypersensitivity reactions consisting of lid edema, itching, increased redness, tearing, and/or circumocular rash. Photosensitivity has been reported in patients taking oral trimethoprim.

To report SUSPECTED ADVERSE REACTIONS, contact Bausch & Lomb Incorporated at 1-800-553-5340 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

In mild to moderate infections, instill one drop in the affected eye(s) every 3 hours (maximum of 6 doses per day) for a period of 7 to 10 days.

HOW SUPPLIED

NDC 68788-8152-1 10 mL

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Polymyxin B
Sulfate and
Trimethoprim
Ophthalmic
Solution, USP*
(Sterile)

FOR TOPICAL
APPLICATION
IN THE EYE

Rx only

10 mL

BAUSCH + LOMB

Relabeled By: Preferred Pharmaceuticals Inc.

9534002
AB31509

POLYMYXIN B SULFATE AND TRIMETHOPRIM				
polymyxin b sulfate and trimethoprim sulfate solution/ drops				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68788-8152(NDC:24208-315)	
Route of Administration	OPHTHALMIC			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)		POLYMYXIN B	10000 [USP'U] in 1 mL	
TRIMETHOPRIM SULFATE (UNII: E377MF8EQ8) (TRIMETHOPRIM - UNII:AN164J8Y0X)		TRIMETHOPRIM	1 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SULFURIC ACID (UNII: O40UQP6WCF)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)				
Packaging				
#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:68788-8152-1	1 in 1 CARTON	03/14/2022	
1		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA064120	03/14/2022	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-8152)

Revised: 9/2023

Preferred Pharmaceuticals Inc.